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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/592,956	07/25/2007	Yoshihiko Abe	1029650-000176	8661

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BUCHANAN, INGERSOLL & ROONEY PC
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EXAMINER

HEINCER, LIAM J

ART UNIT	PAPER NUMBER
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1796

NOTIFICATION DATE	DELIVERY MODE
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06/03/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com

Office Action Summary	Application No. 10/592,956	Applicant(s) ABE ET AL.	
	Examiner Liam J. Heincer	Art Unit 1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/2006 and 7/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Considering Claim 10: Claim 10 requires the polysaccharide to be free of carboxy groups. However, the method of preparation provided in the original specification requires a carboxyl or carboxyalkyl group (¶0059). Therefore it is unclear how the material can be produced from a polysaccharide comprising no carboxyl or carboxyalkyl groups. For the purpose of further examination the term "raw material" is being considered to mean a polysaccharide to which a carboxy group must be introduced prior to esterification, such as dextran, as implied by the original specification (¶0013).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-20 are rejected under 35 U.S.C. 102(a) as being anticipated by Abe et al. (WO 2004/081055). Note: US 2006/0178339 is being used as an English language equivalent for WO 2004/081055 and all citations will be directed towards the US

Art Unit: 1796

document. Additionally, the document has a publication date prior to the earliest effective US filing date, but later than the foreign priority document. The reference may then be removed as prior art through the furnishing of a certified translation of the priority document.

Considering Claim 1: Abe et al. teaches a composition comprising a crosslinkable polysaccharide comprising at least one active ester group which has been introduced into a polysaccharide side chain, which is capable of reacting with an active hydrogen containing group, and forming a crosslinked material through a covalent bond between the active ester group and the active hydrogen containing group in the presence of water under alkaline conditions (¶0016).

Considering Claim 2: Abe et al. teaches the active hydrogen as being a hydroxyl group in a polysaccharide molecule and the polysaccharide derivative as being self-crosslinking (¶0017).

Considering Claims 3 and 15: Abe et al. teaches the hydroxyl group as being on a living organism (¶0018).

Considering Claims 4, 5, and 16: Abe et al. teaches the activating group as being a hydroxyamine (¶0020).

Considering Claims 6 and 17: Abe et al. teaches ester group as being present in an amount of 0.1 to 2 mmoles/g (¶0022).

Considering Claims 7 and 18: Abe et al. teaches polysaccharide as further containing a carboxy or carboxyalkyl group (¶0023).

Considering Claims 8 and 19: Abe et al. teaches the derivative as being a non-salt (¶0024).

Considering Claim 9: Abe et al. teaches the raw polysaccharide as being soluble in an aprotic polar solvent at a temperature of between 60 and 120 °C under the claimed conditions (¶0025).

Considering Claim 10: Abe et al. teaches the original polysaccharide as having no carboxy or carboxyalkyl groups (¶0026).

Considering Claim 11: Abe et al. teaches the alkaline condition as being a pH of from 7.5 to 12 (¶0029).

Art Unit: 1796

Considering Claim 12: Abe et al. teaches a composition comprising a second polymer (¶0045).

Considering Claim 13: Abe et al. teaches adding a pH adjuster to the composition (¶0060).

Considering Claim 14: Abe et al. teaches a composition comprising a second polymer (¶0045).

Considering Claim 20: Abe et al. teaches reacting the material in the presence of water under alkaline conditions (¶0066).

Claims 1-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Barbucci et al. (WO 00/27886).

Considering Claims 1-5, 11, 15, and 16: Barbucci et al. teaches a composition comprising a crosslinkable polysaccharide (4:12-13) that has been derivatized by an active ester group forming compound, such as hydroxysuccinimide (5:10-15).

The limitations “capable of reacting...” and “capable of forming...” are considered to be functional language. As a polysaccharide with the claimed structure would inherently be capable of reaction with an active hydrogen containing group to form a crosslinked material the claimed limitations are considered met. Additionally, further limitations on the nature of the active hydrogen containing group or reaction conditions in the dependent claims would not alter the structure of the polysaccharide derivative and therefore have been given little patentable weight.

Considering Claims 6 and 17: Barbucci et al. teaches a degree of substitution of 50 mol% per carboxyl group (Example 8). As a repeat unit has a molecular weight of ~360 g/mol, there are 2.75 mmol/g for 100% substitution. Therefore 50% substitution is ~1.38 mmol/g.

Considering Claim 7 and 18: Barbucci et al. teaches the polysaccharide as having carboxy groups (4:17-18). Since their would not be 100% yield in the process and polysaccharide already contains carboxy groups, the derivative would also contain carboxy groups.

Art Unit: 1796

Considering Claim 8 and 19: Barbucci et al. teaches the product as optionally being a salt/optionally being a non-salt (4:22-23).

Considering Claim 9: Barbucci et al. teaches the same polysaccharides as in the instant specification (4:24-5:5). Therefore it is assumed that the polysaccharides would have the same solubility in solvent.

Considering Claim 10: Barbucci et al. teaches the polymer as being a dextran derivative (4:24-27).

Considering Claim 12: Barbucci et al. teaches mixing the polysaccharide with a polyamine polymer (5:16-26).

Considering Claim 13: Barbucci et al. teaches adding a base/pH adjuster to the crosslinkable composition (6:9-12).

Considering Claim 14: Barbucci et al. teaches mixing the polysaccharide with a polyamine polymer (5:16-26).

Claims 1-5, 7, 9, 11, 15, 16, 18, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Aeschlimann et al. (US Pat. 6,630,457).

Considering Claims 1-5, 11, 15, and 16: Aeschlimann et al. teaches a composition comprising a crosslinkable (16:8-11) activated ester of hyaluronic acid and hydroxysuccinimide (16:20-33).

The limitations “capable of reacting...” and “capable of forming...” are considered to be functional language. As a polysaccharide with the claimed structure would inherently be capable of reaction with an active hydrogen containing group to form a crosslinked material the claimed limitations are considered met. Additionally, further limitations on the nature of the active hydrogen containing group or reaction conditions in the dependent claims would not alter the structure of the polysaccharide derivative and therefore have been given little patentable weight.

Considering Claim 7 and 18: Aeschlimann et al. teaches the polysaccharide as being hyaluronic acid/a polysaccharide having carboxy groups (16:8-11). Since their would not be 100% yield in the process and polysaccharide already contains carboxy groups, the derivative would also contain carboxy groups.

Considering Claim 9: Aeschlimann et al. teaches one the polysaccharides disclosed in the original specification. Therefore it is assumed that the polysaccharides would have the same solubility in solvent.

Considering Claim 20: Aeschlimann et al. teaches crosslinking the activated ester in water under alkaline conditions (Example 9).

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO form 892.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5, 11, 12, 15, and 16 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 16 of copending Application No. 10/546,256. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 16 teaches a composition comprising a species of the claimed polysaccharide derivative and a second polymer.

Claims 1-5 and 11-16 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 18 of copending Application No. 10/546,256. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 18 teaches a composition comprising a species of the claimed polysaccharide derivative, a pH adjusting agent, and a second polymer.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Liam J. Heincer whose telephone number is 571-270-3297. The examiner can normally be reached on Monday thru Friday 7:30 to 5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Eashoo can be reached on 571-272-1197. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1796

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MARK EASHOO/

LJH

Supervisory Patent Examiner, Art Unit 1796

May 6, 2008

20-May-08